

SEP 13 2007

Application No. 10/706,128

Reply to Office Action

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Currently Amended) A An essentially anhydrous pharmaceutical composition for oral administration, which is directly orally administered without liquid and without chewing, comprising at least one pharmaceutical active ingredient in an effective amount and comprising one or more coated particles which have a core containing the at least one pharmaceutical active ingredient, and have a coating consisting of one or more layers, wherein

(a) the coating layer or the coating layers contain at least one hydratable, pharmaceutically acceptable polymer which, on contact with saliva saliva, or water, forms a coherent, mouldable, viscous, viscous particle paste mass which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the mass, particle paste, and release of active ingredient in the mouth, and

(b) the coating layer or the outermost of the coating layers contains an effective amount of at least one a salivation-promoting agent in an amount which is effective, upon said oral administration of the composition, in promoting a flow of saliva which is sufficient to form said coherent, mouldable, viscous particle paste within less than 20 seconds.

2. (Previously Presented) The composition according to claim 1, which comprises as hydratable polymer a nonionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 10,000 mPa·s or an ionic polymer with a viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of from 3 to 30,000 mPa·s.

3. (Previously Presented) The composition according to claim 1 which comprises as hydratable polymer methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone, sodium carboxymethylcellulose, polyacrylic acid, polyacrylate, alginic acid, alginate, pectin, xanthan, galactomannan, ~~guar gum, hydroxypropyl-guar gum, gelatin and/or gum arabic.~~

4. (Previously Presented) The composition according to claim 1, which comprises a hydratable polymer with a viscosity, measured as 1% strength (weight/weight) aqueous

Application No. 10/706,128

Reply to Office Action

solution at 25°C, of at least about 25 mPa·s.

5. (Previously Presented) The composition according to claim 1, wherein the hydratable polymer has an average particle size not exceeding 200 μm .

6. (Previously Presented) The composition according to claim 1, wherein the coating is present in an amount of from 5 to 75% by weight, based on the essentially anhydrous composition.

7. (Previously Presented) The composition according to claim 1, which comprises as pharmaceutical active ingredient loperamide, mesalazine, olsalazine, cimetidine, ranitidine, famotidine, nizatidine, omeprazole, sucralfate, pantoprazole, pancreatin, bisacodyl, lactulose, acetylsalicylic acid, paracetamol, ibuprofen, morphine, tramadol, naproxen, diclofenac, piroxicam, terfenadine, astemizole, ambroxol, acetylcysteine, theophylline, atenolol, nifedipine, diltiazem, verapamil, isosorbide mononitrate, amitriptyline, nitrazepam, budesonide, ciprofloxacin, norfloxacin, ofloxacin, amoxicillin, cefaclor, cefadroxil, tetracycline, erythromycin, a pharmaceutically acceptable salt of one of these active ingredients, or a combination of two or more of these active ingredients and salts.

8. (Currently Amended) The composition according to claim 1, which comprises as the salivation-promoting agent a water-soluble organic acid or a water-soluble salt of a water-soluble organic acid and/or a water-soluble, osmotically active substance.

9. (Currently Amended) The composition according to claim 1, which comprises as the salivation-promoting agent tartaric acid, citric acid, malic acid, ascorbic acid, a sodium or potassium salt of these acids, glucose, fructose, sucrose, xylitol, mannitol, sorbitol, maltitol or a combination of two or more of these compounds.

10. (Previously Presented) The composition according to claim 1, wherein the coating consists of two or more layers, and the viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of the hydratable polymer in a layer of the coating is in each case no greater than the viscosity, measured as 1% strength (weight/weight) aqueous solution at 25°C, of the hydratable polymer in the adjacent inner layer of the coating.

11. (Currently Amended) The composition according to claim 10, wherein the

Application No. 10/706,128

Reply to Office Action

outermost layer of the coating comprises a hydratable polymer with a viscosity of from 25 to 5000 5,000 mPa·s, and the second outermost layer of the coating comprises a nonionic hydratable polymer with a viscosity of from 5000 5,000 to 10,000 mPa·s and/or an ionic hydratable polymer with a viscosity of from 5000 5,000 to 30,000 mPa·s, where the viscosities in each case relate to the viscosity of a 1% strength (weight/weight) aqueous solution of the polymer measured at 25°C.

12. (Currently Amended) The composition according to claim 10, wherein the outermost layer of the coating comprises polyvinylpyrrolidone or a cellulose ether with a viscosity of from 25 to 5000 5,000 mPa·s, and the second outermost layer of the coating comprises sodium carboxymethylcellulose with a viscosity of from 5000 to 8000 5,000 to 8,000 mPa·s, polyacrylic acid with a viscosity of from 5000 5,000 to 30,000 mPa·s or a cellulose ether with a viscosity of from 5000 5,000 to 10,000 mPa·s, where the viscosities in each case relate to the viscosity of a 1% strength (weight/weight) aqueous solution of the polymer measured at 25°C.

13. (Previously Presented) The composition according to claim 10, wherein a hydratable polymer with an average particle size not exceeding 50 µm is used in the second outermost layer of the coating.

14. (Previously Presented) The composition according to claim 10, wherein the second outermost layer of the coating is present in an amount of from 0.25 to 50% by weight, calculated as essentially anhydrous layer and based on the essentially anhydrous active ingredient-containing core, and the outermost layer of the coating is present in an amount of from 3 to 60% by weight, calculated as essentially anhydrous layer and based on the essentially anhydrous composition.

15. (Previously Presented) The composition according to claim 10, wherein the core has a taste-masking coating layer which is resistant to gastric fluid or delays the release of active ingredient.

16. (Previously Presented) The composition according to claim 1, wherein the coated particles have a maximum diameter of from 0.25 to 12 mm.

17. (Currently Amended) The composition according to claim 1, wherein which

Application No. 10/706,128

Reply to Office Action

comprises several coated particles, and the mouldable mass particle paste formed on contact with saliva causes the particles to stick together.

18. - 20. (Canceled)

21. (Withdrawn) A process for producing the pharmaceutical composition defined in claim 1, wherein one or more particles comprising at least one pharmaceutical active ingredient in an effective amount are coated with one or more layers, where

(a) the layer or layers comprise at least one hydratable, pharmaceutically acceptable polymer which, on contact with saliva or water, forms a coherent, mouldable, viscous mass which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the mass, and active ingredient being released in the mouth, and

(b) the layer or the outermost layer comprises an effective amount of at least one salivation-promoting agent, optionally the coated particles are converted with pharmaceutical ancillary substances into a pharmaceutical presentation, and optionally, the composition is mixed with water in an amount of up to about 300% by weight, based on the essentially anhydrous composition.

22. (Canceled).

23. (Currently Amended) A medicinal product pack comprising a pharmaceutical composition according to claim 1 and the instructions that the composition be taken by direct administration into the mouth without liquid and without chewing or, before intake, be mixed with a metered amount of from 30 to 300% by weight of water, based on the essentially anhydrous pharmaceutical composition.

24. (Withdrawn) A method for treating or preventing diseases by oral administration of a pharmaceutical composition, comprising the production of the pharmaceutical composition defined in claim 1, and optionally adding a metered amount of from 30 to 300% by weight of water, based on the essentially anhydrous composition, and directly administering the composition into the mouth.

25. (New) A pharmaceutical composition for oral administration, comprising at least one pharmaceutical active ingredient in an effective amount and comprising coated

Application No. 10/706,128

Reply to Office Action

particles which have a core containing the at least one pharmaceutical active ingredient, and have a coating consisting of one or more layers, wherein

- (a) the coating layer or the coating layers contain at least one hydratable, pharmaceutically acceptable polymer which, on contact with saliva, forms a coherent, mouldable, viscous particle paste which is slippery on the surface and does not adhere to the oral mucosa, and which prevents active ingredient-containing particles escaping from the paste, and release of active ingredient in the mouth, and
- (b) the coating layer or the outermost of the coating layers contains an effective amount of at least one salivation-promoting agent selected from the group consisting of malic acid, ascorbic acid, a sodium or potassium salt of these acids, glucose, xylitol, mannitol, sorbitol, maltitol or a combination of two or more of these compounds.